Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of postoperative analgesic effect of intravenous acetaminophen versus intravenous caffeine in distal radius surgery

Protocol summary

Study aim
Determining and comparing the analgesia effect of injectable acetaminophen with injectable caffeine in distal radius surgeries

Design
A double-blind clinical trial with a control group, with parallel groups, randomized, phase 3, the number of 30 samples in each group is estimated. Allocation of samples to intervention groups is done using color cards method.

Settings and conduct
This study is conducted on patients referred to the Shahid Rajaei educational-therapeutic center in Qazvin city, who are candidates for distal radius surgery according to the order of the orthopedic surgeon. Test group A (acetaminophen injection drug 10mg/kg), test group C (caffeine injection drug 1mg/kg) and control group O (normal saline 10 cc) after fully regaining consciousness and expressing pain, it is infused to the patient in 100 cc of normal saline diluted by microset over 30 minutes. The participant and outcome evaluator are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 20 and 60 years old; distal radius fracture; general anesthesia. Exclusion criteria: unwillingness to cooperate in the study; heart patients with a history of HTN (heart rate over 100 during surgery/blood pressure over 140 during surgery); occurrence of any problems and complications during the study; pregnancy; breastfeeding and abortion less than 3 months; allergy to acetaminophen/caffeine/morphine; long-term use of corticosteroids, antihistamines, narcotics and painkillers; vision and hearing problems and other disabilities; chronic mental and physical illness; liver patients; history of smoking, alcohol and drugs; the duration of the surgery is less than 45 minutes.

Intervention groups
Test group A (acetaminophen injection drug 10mg/kg), test group C (caffeine injection drug 1mg/kg) and control group O (normal saline 10 cc)

Main outcome variables
The amount and intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230716058807N1**
Registration date: **2023-08-01, 1402/05/10**
Registration timing: **prospective**

Last update: **2023-08-01, 1402/05/10**
Update count: **0**

Registration date
2023-08-01, 1402/05/10

Registrant information

Name
Hamed Talayeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 28 3379 0628

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hamed_talayeh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-06, 1402/05/15

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of postoperative analgesic effect of intravenous acetaminophen versus intravenous caffeine in distal radius surgery

Public title
Comparison of postoperative analgesic effect of intravenous acetaminophen versus intravenous caffeine in distal radius surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in research with informed consent after giving necessary and sufficient explanations about the study Age 20 to 60 years Distal radius fracture General anesthesia
Exclusion criteria:
Unwillingness to cooperate in the study Cardiac patients with a history of HTN (heart rate over 100 during surgery/blood pressure over 140 mm Hg during surgery) Occurrence of any problems and complications during the study Pregnancy, breastfeeding and abortion less than 3 months Allergy to acetaminophen/caffeine/morphine Long-term use of corticosteroids, antihistamines, narcotics and pain relievers Vision and hearing problems and other disabilities Chronic mental and physical illness (schizophrenia, diabetes, etc) Liver patients (hepatitis, cirrhosis, etc.) History of smoking, alcohol and drugs The duration of surgery should be less than 45 minutes
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a double-blind randomized clinical trial that is conducted in patients referred to medical training centers of Qazvin University of Medical Sciences who are candidates for distal radius surgery according to the instructions of the orthopedic surgeon. Patients who met the necessary conditions, after full training by an anesthesiologist and filling in the patient's informed personal consent form, entered the study, after randomly selecting the patients, they were divided into three groups, and then the intervention was carried out.In this way: one of the three test groups will be A (acetaminophen drug), test group C (caffeine drug) and control group O (placebo). Sampling is done using the available method. Allocation of samples to intervention groups will be done using color cards method
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind type of experiment, which will be blind for the people participating in the study and evaluating the outcome. In the consent form to participate in the study, it is written for the patient that his presence does not necessarily mean intervention but may be included in the control group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of qazvin University of Medical Sciences
Street address
Research and Technology deputy ,Mavaddat Alley,Shahid Beheshti Blvd,Qazvin
City
Qazvin
Province
Qazvin
Postal code
3413996134
Approval date
2021-11-17, 1400/08/26
Ethics committee reference number
IR.QUMS.REC.1400.329

Health conditions studied

1

Description of health condition studied
distal radius surgery
ICD-10 code
S52.5
ICD-10 code description
Fracture of lower end of radius

Primary outcomes

1

Description
The amount and intensity of pain

Timepoint
1, 3, 6 and 12 hours after the operation
Method of measurement
Using a ruler-like grading system (Visual Analog Scale) from 0 (no pain) to 10 (the most severe pain imaginable)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 10 mg/kg of injectable acetaminophen is diluted in 100 cc of normal saline and infused to the patient over 30 minutes.
Category
Treatment - Drugs

2

Description
Intervention group: 1 mg/kg of injectable caffeine diluted in 100 cc of normal saline is infused to the patient over 30 minutes.
Category
Treatment - Drugs

3

Description
Control group: 10 cc of normal saline is diluted by microset in 100 cc of normal saline and is infused to the patient over 30 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Hospital
Full name of responsible person
Hamed Talayeh
Street address
Safdari Ave., Padegan Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Hamed Talayeh
Position
Resident
Latest degree
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Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available